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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,459	10/08/2003	Richard S. Ginn	16497.3.1	1645

57360 7590 04/28/2010

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EXAMINER	
DORNBUSCH, DIANNE	
ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
04/28/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/682,459	GINN ET AL.	
	Examiner	Art Unit	
	DIANNE DORNBUSCH	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5,7-10,14-16 and 20-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5,7-10,14-16 and 20-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/30/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 23, 2010 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 2, 3, 5, 7-10, 14-16, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. (5,674,231) in view of Fontaine et al. (6,447,540) and further in view of Kanner et al. (5,868,755).

Green discloses the following claimed limitations:

Claim 2: A method for delivering a closure element (22) to seal an opening through tissue (Col. 1 Lines 5-10), the closure element being carried on a carrier assembly (42) slidably disposed on a proximal end of an elongate member (34) (note that the carrier assembly is placed in the proximal portion of the elongated member and then pushed forward in order to move the closure element) such that a proximal end of the closure

element is spaced apart from an outer surface of the elongate member (Fig. 2), the method comprising: inserting a distal end of the elongate member into an opening through tissue (Fig. 15), the elongate member having a distal end and a proximal end (Fig. 4); advancing the carrier assembly distally along the elongate member from the proximal end towards the distal end of the elongate member (Fig. 4 and 15-20), thereby advancing the closure element towards the distal end of the elongate member (Fig. 4 and 15-20); engaging tissue adjacent the distal end of the elongate member with a plurality of tissue engaging elements (each leg of the closure element) on the closure element (Fig. 22); and withdrawing the elongate member from the opening, thereby leaving the closure element to close the opening (Col. 8 Lines 49-52).

Claim 8: Wherein the opening through tissue extends through one or more layers of fascia, and wherein the skin facilitates advancing the closure element through the one or more layers of fascia (Fig. 11 where a plurality of layers of fascia have to be passed in order to reach the blood vessel).

Claim 9: Wherein the opening through tissue communicates with a blood vessel (104), and wherein leaving the closure element to close the opening comprises leaving the closure element to substantially seal the opening from blood flow therethrough with the closure element (Fig. 22 and Col. 8 Lines 49-52).

Claim 10: Wherein the elongate member comprises a lumen (34a) extending between the proximal and distal ends (Fig. 4), and wherein the method further comprises inserting one or more instruments through the lumen into the blood vessel (Col. 6 Lines 56-58 where instrument 60 is placed through the lumen).

Claim 14: Inserting a distal end of an actuator member (44a, 44b) between the proximal end of the closure element and the outer surface of the elongate member until the distal end of the actuator member is coupled with the closure element and advancing the actuator member in a distal direction to advance the carrier assembly along the elongate member (Fig. 18).

Claim 15: Manipulating the actuator member to deploy the closure element and engage the tissue adjacent the distal end of the elongate member (Fig. 4 and 15-20).

Claim 16: Wherein engaging tissue adjacent the distal end of the elongate member with tissue engaging elements on the closure element comprises deploying the closure element from the carrier assembly and elongate member, the closure element comprising a generally annularly-shaped body comprising proximal and distal ends and a plurality of tissue engaging portions extending from the distal end, the closure element being configured to move from a first expanded configuration when on the carrier assembly to a second contracted configuration when deployed, thereby drawing tissue around the opening together (Fig. 4 and 15-20).

Green discloses the claimed invention, including advancing the carrier assembly towards the distal end, except for a skin, or sleeve member, overlying at least a portion of the outer surface between the carrier assembly and a distal end of the elongate member and the carrier assembly causing the skin to separate from the outer surface of the elongate member, the skin comprising a weakened region extending towards the distal end of the elongate member and expanding to a cross-section that is larger than a cross-section of the elongate member as the carrier assembly is advanced, and the skin

comprising an outer surface that is substantially slippery for facilitating advancement of the elongate member into the opening through tissue.

Fontaine teaches a skin or sleeve (16) with a weakened region overlying at least a portion of an outer surface between a carrier assembly (20) and a distal end of an elongate member (12) and the carrier assembly may cause the skin to separate or split from the outer surface of the elongate member and expand as it advances or moves longitudinally (see abstract and Figure 7). Fontaine also teaches a slippery surface on the sleeve (col. 7, lines 29-38).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Green with a splittable skin with a slippery surface, as taught by Fontaine, since it was known in the art that skins or sheaths are commonly used in deployment devices to conveniently protect delivery devices and splittable sleeves facilitate unveiling of the delivery device without retraction (col. 2, lines 47-57).

Green in view of Fontaine disclose the claimed invention, including the carrier assembly advancing towards the distal end except for the skin being bonded to the outer surface of the elongate member by an adhesive and wherein the adhesive has sufficient adhesive strength such that the skin may be peeled away from the outer surface.

Kanner teaches a skin 1 being bonded to the outer surface of the elongate member by an adhesive and wherein the adhesive has sufficient adhesive strength such that the skin may be peeled away from the outer surface (col. 4, lines 1-16).

It would have been obvious to one of ordinary skill in the art to provide Green in view of Fontaine with a skin bonded to the outer surface to the elongate member, as taught by Kanner, since it was known in the art to provide adhesives that provide temporary security and to avoid undesired movement of the sheath.

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. (5,674,231) in view of Fontaine et al. (6,447,540) and Kanner et al. (5,868,755) and further in view of Martinez (5,593,412).

Green in view of Fontaine and Kanner disclose the claimed invention, except for the skin comprising a flap extending generally axially along the outer surface of the elongate member and overlying an adjacent region of the skin, and wherein the flap is released from the adjacent region as the carrier assembly is advanced towards the distal end of the elongate member, thereby allowing the skin to separate from the outer surface.

Martinez teaches the skin (18) comprising a flap (fingers 51-55) extending generally axially along the outer surface of the elongate member (12) and overlying an adjacent region of the skin (Fig. 1-3 where the flaps are adjacent to the weakend areas (41-45) which attaches all he fingers together as best seen in Fig. 2A) fingers as seen in the figures), and wherein the flap is released from the adjacent region (Fig. 2B-5) as the carrier assembly (14) is advanced towards the distal end of the elongate member, thereby allowing the skin to separate from the outer surface (Fig. 2-5).

It would have been obvious to one of ordinary skill to provide a skin with flaps, as taught by Martinez, to Green in view of Fontaine and Kanner in order to have a closed

tapered area which would facilitate insertion through the tissue prior to separating the skin.

5. Claims 20-31, 33, 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. (5,674,231) in view of Fontaine et al. (6,447,540) and Kanner et al. (5,868,755) and further in view of Martinez (5,593,412).

Green discloses the following claimed limitations:

Claim 20: A method for delivering a closure element (22) to seal an opening through tissue (Col. 1 Lines 5-10), the closure element being carried on a carrier assembly (42) slidably disposed on a proximal end of an elongate member (34) (note that the carrier assembly is placed in the proximal portion of the elongated member and then pushed forward in order to move the closure element) such that a proximal end of the closure element is spaced apart from an outer surface of the elongate member (Fig. 2), the method comprising: inserting a distal end of the elongate member into an opening through tissue (Fig. 15), the elongate member having a distal end and a proximal end (Fig. 4); inserting a distal end of an obturator (60) disposed within the elongated member through the opening through tissue (Fig. 15); advancing the carrier assembly distally along the elongate member from the proximal end towards the distal end of the elongate member (Fig. 4 and 15-20), thereby advancing the closure element towards the distal end of the elongate member (Fig. 4 and 15-20); engaging tissue adjacent the distal end of the elongate member with a plurality of tissue engaging elements (each leg of the closure element) on the closure element (Fig. 22); and withdrawing the elongate

member from the opening, thereby leaving the closure element to close the opening (Col. 8 Lines 49-52).

Claim 21: See rejection claim 16

Claim 22: Wherein the obturator comprises an expandable distal portion (combination 62 and 64) coupled with an elongate portion (68) extending proximally for manipulation by a user (Fig. 8-10).

Claim 23: Retracting the elongate portion of the obturator in a proximal direction to expand the expandable distal portion distal of the opening through tissue to stabilize or secure tissue surrounding the opening (Fig. 12-15).

Claim 27: See rejection of claim 14

Claim 28: See rejection of claim 15

Claim 29: See rejection claims 1, 10, and 20

Claim 30: See rejection claim 16

Claim 36: See rejection of claim 9

Claims 37-39: See rejection claims 20, 22, and 23. Note that the instrument that is inserted in the device is the obturator.

Green discloses the claimed invention, including advancing the carrier assembly towards the distal end, except for a skin, or sleeve member, overlying at least a portion of the outer surface between the carrier assembly and a distal end of the elongate member and the carrier assembly causing the skin to separate from the outer surface of the elongate member, the skin comprising a weakened region extending towards the distal end of the elongate member and expanding to a cross-section that is larger than a

cross-section of the elongate member as the carrier assembly is advanced, and the skin comprising an outer surface that is substantially slippery for facilitating advancement of the elongate member into the opening through tissue.

Fontaine teaches a skin or sleeve (16) with a weakened region overlying at least a portion of an outer surface between a carrier assembly (20) and a distal end of an elongate member (12) and the carrier assembly may cause the skin to separate or split from the outer surface of the elongate member and expand as it advances or moves longitudinally (see abstract and Figure 7). Fontaine also teaches a slippery surface on the sleeve (col. 7, lines 29-38) and that the skin comprises embedded fibers (82, 66) to bias the skin to preferentially tear (Fig. 14 and 16).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify Green with a splittable skin with a slippery surface, as taught by Fontaine, since it was known in the art that skins or sheaths are commonly used in deployment devices to conveniently protect delivery devices and splittable sleeves facilitate unveiling of the delivery device without retraction (col. 2, lines 47-57).

6. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. (5,674,231) in view of Fontaine et al. (6,447,540) and further in view of Martinez (5,593,412).

Green in view of Fontaine disclose the claimed invention, except for the skin comprising a flap extending generally axially along the outer surface of the elongate member and overlying an adjacent region of the skin, and wherein the flap is released

from the adjacent region as the carrier assembly is advanced towards the distal end of the elongate member, thereby allowing the skin to separate from the outer surface.

Martinez teaches the skin (18) comprising a flap (fingers 51-55) extending generally axially along the outer surface of the elongate member (12) and overlying an adjacent region of the skin (Fig. 1-3 where the flaps are adjacent to the weakend areas (41-45) which attaches all he fingers together as best seen in Fig. 2A) fingers as seen in the figures), and wherein the flap is released from the adjacent region (Fig. 2B-5) as the carrier assembly (14) is advanced towards the distal end of the elongate member, thereby allowing the skin to separate from the outer surface (Fig. 2-5).

It would have been obvious to one of ordinary skill to provide a skin with flaps, as taught by Martinez, to Green in view of Fontaine in order to have a closed tapered area which would facilitate insertion through the tissue prior to separating the skin.

Response to Arguments

7. Applicant's arguments with respect to the arguments filed March 23, 2010 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773